

PATENT

Serial No: 10/092,237
Filed: March 6, 2002
Applicant: Boyce
Title: SURGICAL DEVICE FOR SKIN THERAPY OR TESTING
Art Unit: 1636
Examiner: Kaushal
Conf. No.: 8680
Atty Dock: CUT-01

Cincinnati, Ohio 45202

March 26, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF STEVEN T. BOYCE, Ph.D.

I, Steven T Boyce, declare as follows:

(1) I am the inventor of the claimed subject matter in the above-identified application.

(2) I received my Doctor of Philosophy degree from the University of Colorado, in the field of molecular, cellular and developmental biology. I have 29 years of experience in biomedical research. In particular, I have 21 years of experience in the field of skin science research, which is the subject of this application.

(3) I have read the outstanding Office Action and references cited, participated in the March 25, 2004 telephone interview with the Examiner, and understand the position of the Examiner.

(4) I respectfully disagree with the Examiner's position that the publication (Boyce, Med. Biol. Eng. & Comp. 36:791-800, 1998) anticipates the claimed invention. As I understand it, the Examiner's position is that Figure 1 in the publication discloses the claimed cultured skin device. I disagree for the following reasons.

(5) Figure 1, as stated in the figure legend, discloses that "Cultured human keratinocytes (HK) [keratinocytes are epidermal cells] in vitro organize to form stratified squamous epithelium attached to dermal substitute composed of cultured human fibroblasts and collagen-GAG substrate C-GAG-HF)." Thus, Figure 1 discloses a biocompatible reticulated matrix that is filled uniformly and entirely with cultured dermal cells (fibroblasts). This is indicated in the legend as "cultured human fibroblasts and collagen-GAG substrate C-GAG-HF".

(6) This is not the claimed cultured skin device. Specifically, the claimed cultured skin device contains "cultured dermal cells on a biocompatible reticulated matrix" (claim 1, emphasis added). Figure 1 in the publication discloses

a matrix uniformly filled with dermal cells. In contrast, in the claimed device, the dermal cells are distributed asymmetrically on the biocompatible reticulated matrix.

(7) The claims also recite that the dermal cells provide a cellular lamination layer. In my opinion, this additionally indicates that the dermal cells do not fill the matrix.

(8) I further understand that a reference that is cited as anticipating the claimed invention must fully enable the claimed invention. In my opinion, Figure 1 does not enable the claimed invention. As one example, it is not enabling because it does not teach a device with dermal cells on a matrix. As another example, it does not teach how to prepare a device with dermal cells on a matrix.

(9) It is my understanding that the Examiner requests additional clarity regarding the population of dermal and epidermal cells. Specifically, the Examiner questions the recitation of stem cells as members of both the group of epidermal cells recited in dependent claim 2, and the group of dermal cells recited in dependent claim 3.

(10) In my opinion, the claims pending clearly reflect this distinction. Stem cells from post-natal individuals may be progenitors of either epidermal cells or dermal cells, but not both. The references to stem cells in claims 2 and 3 clearly refer to distinct populations and sources of cells from post-natal individuals, at least because claim 2 is limited to epidermal cells, and claim 3 is limited to dermal cells. However, and solely to facilitate prosecution, claims 2 and 3 are amended to clarify this fact.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the subject application or any patent issued thereon.

25 MARCH 2004
Date

Steven T. Boyce Ph.D.
Steven T. Boyce, Ph.D.